

**20.1 MANAGEMENT OF ENVIRONMENTAL DATA**

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Companywide	Program Requirements Document	For Additional Info: <a href="http://EDMS">http://EDMS</a>	Effective Date: 11/11/02
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Manual: 13A-Quality and Requirements Management Program Documents

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## 1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for *environmental data* (see def.) or sample collection; data review/validation, usability, and evaluation; and reporting activities. Implementation of these requirements will assure that environmental data produced by or for Idaho National Engineering and Environmental Laboratory (INEEL) organizations are of sufficient quality to meet management's and user's intended application(s). See Appendix A for requirements basis.

## 2. APPLICABILITY

This PRD applies to company organizations and procured subcontractors involved in the collection, evaluation, and use of environmental data, including analytical data supporting Resource Conservation and Recovery Act of 1988 (RCRA) and mixed waste characterizations. Externally driven programs for characterization of mixed wastes, such as the Waste Isolation Pilot Plant (WIPP) Transuranic (TRU) Waste Characterization Program, may have additional quality and technical requirements as specified in their individual program planning documents. Appendix B lists typical environmental data activities.

The planning and conduct of research and development studies to provide sufficient data to formulate the scope or objectives of an environmental project are governed by DOE Environmental Restoration (ER) STD-6001-92, and are exempt from the requirements of this document.

The requirements identified in this document also apply to the collection and evaluation of environmental data to be used for *design input* (see def.) to engineering projects.

## 3. RESPONSIBILITIES

### 3.1 Quality Assurance Organization

The Quality Assurance Organization is responsible for developing, maintaining, and interpreting the requirements of this PRD. This organization is also responsible for developing the company implementation *process* (see def.) for this PRD, periodically evaluating the effectiveness of this process, and developing and executing any *corrective actions* (see def.) associated with programmatic process deficiencies.

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**3.2 Project Quality Assurance Officer/Manager**

The Project Quality Assurance Officer/Manager (PQAO) is responsible for assessing the implementation of the associated *quality assurance project plan* (QAPjP; see def.) and for approving the QAPjP and subsequent revisions to the QAPjP.

**3.3 Cognizant Quality Engineers**

*Cognizant quality engineers* (CQE; see def.) are responsible for assisting in developing and revising QAPjPs, and assessing their implementation.

**3.4 Program/Project Managers**

Program/project managers (PMs) are responsible for approving QAPjPs and ensuring that they are prepared, maintained, and implemented; and that the usefulness of resulting data are evaluated in accordance with this document and project-specific QAPjPs and *procedures* (see def.).

Program/project managers, assisted by Environmental Affairs, are also responsible for ensuring identification and control of operational *environmental aspects* (see def.) through implementation of applicable environmental management systems and compliance requirements.

**3.5 Organizations Involved in Field Work**

Organizations involved in field work (collecting and submitting environmental samples or conducting environmental measurements) are responsible for implementing the applicable QAPjP, *sampling and analysis plan* (SAP; see def), and or *field sampling plan* (FSP; see def.) and completing field work as prescribed in work control documents.

**3.6 Analytical Services**

Organizations or vendors delivering analytical services in support of projects and QAPjPs are responsible for all administrative, analytical, and quality control requirements specified in the statements of work (SOW) and work control documents.

**NOTE:** *The appropriate QAPjP should be referenced in the work control documents.*

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**3.7 Data Validators and Reviewers**

*Data* (see def.) validators are responsible for validating data and evaluating the limitations of resulting data in accordance with criteria found in the QAPjP, technical SOW, SAP, and analytical method. Data reviewers have a primary responsibility to provide PMs and data users with an overall evaluation of the degree of achievement of project *data quality objectives* (see def.).

**3.8 Data Users**

Data users are responsible for providing input to the preparation of QAPjPs and using and reporting data based on results of data validations and or reviews, technical or regulatory applications.

**3.9 Permitting Staff**

Permitting staff is responsible for reviewing and approving such QAPjPs to ensure inclusion of adequate instructions and quality assurance/quality control with related regulations and permits.

**4. REQUIREMENTS****4.1 Company Applications**

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

**4.1.1 Basic**

**NOTE 1:** *This document establishes requirements for QAPjPs, the subsequent implementation of these plans, assessments of implementation activities, and the validation and or review of resulting environmental data.*

**NOTE 2:** *See Appendix C for a flowchart of data management activities for environmental data.*

4.1.1.1 The adequacy and reliability of environmental data shall be ensured through the preparation and implementation of quality assurance project plans, sampling and analysis plans, field sampling plans, or *waste analysis plans* (WAPS; see def.). Data quality objectives shall be established during project planning. *[Company interpretation of applicable environmental requirements]*

**NOTE:** *For the purpose of this document, QAPjP may also be interpreted as SAP. SAP traditionally refers to a document that performs both the function of a FSP and a QAPjP.*

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- 4.1.1.2 The QAPjPs, in conjunction with the quality assurance program and procedures and Environmental Protection and Compliance manual, constitute the quality system for the collection of environmental samples (or environmental measurements made in field), and the generation, evaluation, and reporting of associated analytical data or field data. *[Company interpretation of applicable environmental requirements]*

**NOTE:** *Appendix D, Environmental QA Requirements Matrix, provides a matrix comparison of quality assurance requirements identified in this document that can serve as additional resources.*

- 4.1.1.3 *Procurement documents* (see def.) associated with environmental sample or data collection, validation and or review, or reporting by INEEL subcontractors shall specify the need for a quality assurance program that is consistent with all applicable company procurement requirements, or mandate the use of an INEEL QAPjP. *[Company interpretation of applicable environmental requirements]*
- 4.1.1.4 All specific elements required by the applicable Environmental Protection Agency (EPA) consensus standard or requirements document shall be addressed in the QAPjP or an explanation given for its absence. *[Company interpretation of applicable environmental requirements]*
- 4.1.1.5 PMs shall ensure that appropriate permitting staff are involved in the review and *approval* (see def.) of QAPjPs that support activities which demonstrate permit-related compliance, for example: RCRA, National Emission Standards for Hazardous Air Pollutants, Clean Air Act, Waste Water Land Application Permit, etc. *[Company interpretation of applicable environmental requirements]*

**4.1.2 Graded Program Application**

- 4.1.2.1 QAPjPs shall be prepared for new and ongoing activities when required by specific environmental regulations, permits, agreements, or DOE orders. When a QAPjP is prepared, each of the essential elements listed the management control procedure on quality program plan/quality assurance project plan development, must be addressed. If a particular element is not relevant to the project under consideration, instruction steps of the procedure must be followed, including a brief explanation of why the element is not relevant. The level of detail to which each element is addressed is dependent on the data quality objectives determined during project design and or planning. *[Company interpretation of applicable environmental requirements]*

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**4.1.3 Implementation of Quality Assurance Project Plans**

- 4.1.3.1 Project activities shall be implemented by qualified personnel in accordance with the approved QAPjP and documents referenced in the QAPjP. *[Company interpretation of applicable environmental requirements]*
- 4.1.3.2 Implementation shall include periodic assessment of project activities against administrative, technical, and quality requirements found in the QAPjP. *[Company interpretation of applicable environmental requirements]*
- 4.1.3.3 Deviations from the QAPjP shall be documented, reported to management, and evaluated with respect to their significance and potential effect on data quality. The effect on data quality shall be reported to management. *[Company interpretation of applicable environmental requirements]*
- 4.1.3.4 During implementation, any significant changes to the QAPjP will require the same approvals as the original QAPjP. Field level changes may be allowed at the discretion of the PM, but must be approved by the PM and PQAO through a formal documentation process. *[Company interpretation of applicable environmental requirements]*

**4.1.4 Evaluation of Implementation Activities**

- 4.1.4.1 Activities performed during implementation of the QAPjP that affect the quality of data shall be evaluated in accordance with the project self-assessment schedule, or other procedures. *[Company interpretation of applicable environmental requirements]*
- 4.1.4.2 Programmatic deficiencies noted during assessments and nonconforming *items* (see def.) shall be documented and processed per company procedures. *[Company interpretation of applicable environmental requirements]*

**4.1.5 Data Validation and Usability**

- 4.1.5.1 *Analytical method data validation* (see def.), when required, shall be performed and documented independently of the routine data collection process. Responsibilities for analytical data validation are assigned in the QAPjP or *test plan* (see def.). *[Company interpretation of applicable environmental requirements]*

**NOTE:** *Typically, analytical data validation is accomplished via written procedures that identify criteria or characteristics to be validated (see def.) and categorize the results of the validation via application of qualifier “flags” to individual analytical results. Analytical data*

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*validation pertains to that portion of data validation that focuses on the quality of an analytical laboratory's technical performance and methods including any technical or QC requirements derived from the applicable technical statements of work.*

- 4.1.5.2 Data generated during the implementation of a QAPjP shall be systematically reviewed against specified criteria to provide assurance that the data are adequate for intended use. *[Company interpretation of applicable environmental requirements]*
- 4.1.5.3 Data usability reviews shall assess what limitations, if any, should be placed on data usage based on technical reviews and or validation of data. The degree Data Quality Objectives (DQOs) were met by the data is also to be assessed. Minimally, precision, accuracy and completeness are assessed in accordance with specific approved procedures. For additional *guidance* (see def.) on DQOs see references EPA/600R-96/055. *[Company interpretation of applicable environmental requirements]*

**4.1.6 Final Project Report**

- 4.1.6.1 A final report of project activities shall be issued as specified in the agreement, permit, regulations, or DOE Orders. *[Company interpretation of applicable environmental requirements]*
- 4.1.6.2 Reports must include the results of assessments of the overall project and project data, including how well resultant environmental data met the project objectives, the decisions resulting from the project, and possible effects of data quality on the related management decisions. *[Company interpretation of applicable environmental requirements]*

**4.1.7 Records**

- 4.1.7.1 All records designated in implementing documents as *quality assurance records* (see def.) shall be controlled in accordance with the requirements contained in PRD-5088, 17.1 Quality Assurance Records. *[Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]*
- 4.1.7.2 Applicable records requirements of EPA-QA/R-5 and ISO 14001-1996 shall also apply. *[EPA-QA/R-5, A9 and B10; ANSI/ISO 14001-1996, 4.5.3 and Annex A, A.5.3]*

**5. DEFINITIONS**

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

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*analytical method data validation**approval**cognizant quality engineer**corrective action**data**data quality objectives**design input**environmental aspect**environmental data**field sampling plan**guidance**item**procedure**process**procurement document**quality assurance project plan**quality assurance record**sampling and analysis plan**test plan**validate**waste analysis plan***6. REFERENCES**

ANSI/ISO 14001-1996, Environmental Management System – Specification with Guidance for Use, September 23, 1996

Code of Federal Regulations (CFR), 40 CFR 61, Appendix B

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Code of Federal Regulations (CFR), 40 CFR 60, Appendix F

Code of Federal Regulations (CFR), 40 CFR 191

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

DOE Order 5400.1, General Environmental Protection Program, June 1990

EPA/600/R-96-055, Guidance for the Data Quality Objectives Progress, September 1994

EPA QA/R-5, EPA Requirements for Quality Assurance Projects, November 1999

EPA 1980, Office of Research and Development; Interim Guidelines and Specifications for Preparing Quality Assurance project Plans, QAMS-005/80, December

EPA 1991, Office of Research and Development; Preparation Aids for the Development of Category I Quality Assurance Project Plans, EPA/600/8-91/003, February

EPA 1991, Office of Research and Development; Preparation Aids for the Development of Category II Quality Assurance Project Plans, EPA/600/8-91/004, February

EPA 1991, Office of Research and Development; Preparation Aids for the Development of Category III Quality Assurance Project Plans, EPA/600/8-91/005, February

EPA 1990, Quality Assurance Quality Control (QA/QC) Procedures for Hazardous Waste Incineration, January

EPA 1993, Quality Assurance Management Staff; Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process, EPA QA/G-4, Interim Final, October

EPA 1994, Contract Laboratory Program National Functional Guidelines for Organic Data Review, EPA/R-94/012

EPA 1996, EPA Guidance on Total Organics, EPA/600/R-96/036, November

EPA 1998a, Guidance on Collection of Emissions Data to Support Site-Specific Risk Assessments at Hazardous Waste Combustion Facilities, EPA530-D-98-002, August

EPA 1998b, Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, EPA530-D-98-001A, July, Appendix A-1, Table A-1

EPA Guidance Document 530/R94-024, Waste Analysis at Facilities that Generate, Treat, Store, and Dispose of Hazardous (1994)

EPA Quality Assurance Management Staff (QAMS)-005/80; Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans; December 1980



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EPA SW-846; Test Methods for Evaluating Solid Waste; 3rd edition; November 1986

**7. APPENDICES**

Appendix A, 20.1 Basis

Appendix B, Typical Environmental Data Activities

Appendix C, Environmental Data Process Flow Chart

Appendix D, Environmental QA Requirements Matrix

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**APPENDIX A****20.1 Basis**

<b>Source</b>	<b>Citation</b>	<b>Requirement</b>	<b>Comments</b>
ANSI/ISO 14001-1996, Environmental Management Systems – Specification with Guidance for Use	4.5.3 and Annex A A.5.3	4.1.7.2	Consensus Requirement (CR)
EPA-QA/R-5	3.2.9 A9 and 3.3.10 B10	4.1.7.2	Company Imposed Requirement (CIR)
See references in Section 6	Various	4.1.1.1	CIR
See references in Section 6	Various	4.1.1.2	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.1.3	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.1.4	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.1.5	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.2.1	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.3.1	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.3.2	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.3.3	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.3.4	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.4.1	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.4.2	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.5.1	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.5.2	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.5.3	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.6.1	CR - Company interpretation of applicable environmental requirements
See references in Section 6	Various	4.1.6.2	CR - Company interpretation of applicable environmental requirements

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**APPENDIX A****20.1 Basis**

Source	Citation	Requirement	Comments
PRD-5088, 17.1 Quality Assurance Records	All	4.1.7.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements

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**APPENDIX B****Typical Environmental Data Activities**

Environmental data collection activities include all field and laboratory investigations that generate data involving the following:

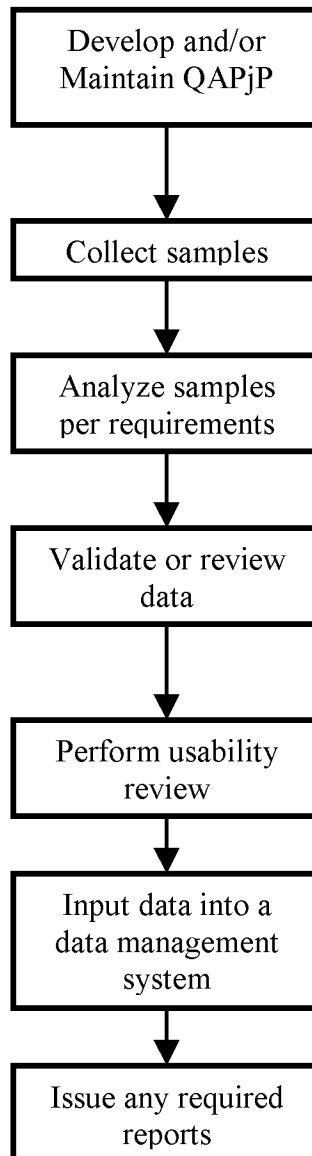
- The measurement of chemical, radiological, physical, or biological parameters in the environment
- Characterization and quantification of waste and effluent discharges to the environment from processes and operations during either a normal or upset condition
- Health and ecological effect studies
- Conduct of clinical and epidemiological investigations
- Performance engineering and process evaluations
- Study of laboratory simulation of environmental events
- Study or measurement on pollutant transport and fate, including diffusion models
- Characterization of waste at generation or before disposal
- Post deactivation, decommissioning, and dismantlement (D&D&D) sampling to verified completion of prescribed activities
- Post-remediation monitoring as prescribed by the Record of Decision
- Characterization of legacy and newly generated waste to determine suitability for transport to and storage at an approved storage facility.

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**APPENDIX C****Environmental Data Process Flow Chart**

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## APPENDIX D

## Environmental QA Requirements Matrix

Program Element	DOE O 5400.1	EPA QAMS 005/80	EPA SW 846	EPA-QA/R-5	40 CFR 61 APPENDIX B NESHAPS	ANSI/ISO-14001
ORGANIZATION	1. Organizational responsibilities	5.4 Project Organization and Responsibility	1.1.3 Organization and Responsibility	A3 Distribution List A4 Project/Task Organization	4.1 Organizational Structure	4.4.1 Structure and Responsibility
PROGRAM DESCRIPTION	2. Program Design	5.3 Project Description	1.1.2 Program Design	A5 Problem Definition/ Background A6 Project/Task Description	4.2 Admin Controls 4.10 Document QA Plan	4.1 General Requirements 4.3.4 Environmental Management Programs
QA OBJECTIVES FOR DATA	2. Program Design	5.5 QA Objectives for Measurement Data	1.1.2 Program Design	A7 Quality Objectives and Criteria for Measurement Data	E4 QA Program Objectives and Precision	4.3.3 Objectives and Targets
SAMPLING PROCEDURES	3. Procedures	5.6 Sampling Procedures	1.2.1 Field QC	B1 Sampling Process Design	4.3 Sample Collection	4.4.6 Operational Control
FIELD QC	4. Field QC	5.11 Internal QC		B2 Sampling Methods B5 Quality Council B6 Instrument/ Equipment Testing, Inspection, and Maintenance B7 Instrument/ Equipment Calibration and Frequency B9 Non-Direct Measurements		4.4.6 Operational Control
LABORATORY QUALITY CONTROL	5. Laboratory Quality Control	5.8 Calibration  5.9 Analytical Procedures	1.2 Analytical QC  1.3 Method Detection Limit	A7 Quality Objectives and Criteria for Measurement Data B4 Analytical Methods	4.3 Analysis Procedure	4.5.1 Monitoring and Measurement

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**APPENDIX D**

Program Element	DOE O 5400.1	EPA QAMS 005/80	EPA SW 846	EPA-QAR-5	40 CFR 61 APPENDIX B NESHAPS	ANSI/ISO-14001
TRANSPORTATION CHAIN-OF-CUSTODY	8. Chain/off-Custody Procedure	5.11 Internal QC	1.5 QC Document	A7 Quality Objectives and Criteria for Measurement Data B3 Sample Handling and Custody	4.6 Sampled Tracking System	4.4.6 Operational Control
	11. Independent Data Verification	5.10 Data Reduction and Reporting	1.4 Data Reporting 1.5 QC Documents	A7 Quality Objectives and Criteria for Measurement Data B10 Data Management		4.5.1 Monitoring and Measurement 4.5 Checking and Corrective Action
		5.14 Assessment Data		D2 Verification and Validation Methods D3 Reconciliation with User Requirements		
REPORTS TO MANAGEMENT	10. Performance Reporting	5.16 QA Reports to Management	1.1.6 QA/QC Reports to Management	A7 Quality Objectives and Criteria for Measurement Data C2 Reports to Management	4.9 Periodic Reports to Management	4.5 Checking and Corrective Action
PERFORMANCE AND SYSTEM AUDITS/ASSESSMENTS	9. Audits	5.12 Performance and System Audits, Frequency	1.1.4 Performance and System Audits	C1 Assessments and Response Actions	4.7 Periodic Internal and External Audits	4.5.4 Environmental Management System Audit
CORRECTIVE ACTION		5.15 Corrective Action	1.1.5 Corrective Action	C1 Assessments and Response Actions	4.8 Corrective Action	4.5.2 Nonconformance and Corrective and Preventive Action 4.5.3 Records
RECORDS	7. Record Keeping			A9 & B10 Documents and Records		Annex A, A.5.3 Records